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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.	╲
08/987,468	12/10/97	GERS-BARLAG	Н	BEIERSDORF	_

HM12/0502

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LAMM, M

ART UNIT PAPER NUMBER
1616 92

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

		Application No.	Applicant(s)					
Office Action Summary		Application No.	Applicant(s)					
		08/987,468	GERS-BARLAG ET AL.  Art Unit					
	•	Examiner	Art Unit					
		Marina Lamm	1616					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply								
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status								
1)🛛	Responsive to communication(s) filed on <u>02 l</u>							
2a) <u></u> □	,	is action is non-final.						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.								
Dispositio	on of Claims							
4)⊠ Claim(s) <u>12-28</u> is/are pending in the application.								
4a) Of the above claim(s) is/are withdrawn from consideration.								
5) 🗌	5) Claim(s) is/are allowed.							
6)🛛	6)⊠ Claim(s) <u>12-28</u> is/are rejected.							
-	,—							
8)	Claims are subject to restriction and/o	r election requirement.						
Application	on Papers							
9) 🗌	The specification is objected to by the Examin	er.						
10)	10) The drawing(s) filed on is/are objected to by the Examiner.							
11)	11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved.							
12)	12) The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. § 119								
	Acknowledgment is made of a claim for foreig	n priority under 35 U.S.C. § 119(	a)-(d) or (f).					
a)[	a) ☐ All b) ☐ Some * c) ☐ None of:							
	1. Certified copies of the priority documents have been received.							
	2. Certified copies of the priority documents have been received in Application No							
<ul> <li>Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>								
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).								
Attachment	(s)							
16) 🔲 Notic	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s)	19) Notice of Inform	ary (PTO-413) Paper No(s) al Patent Application (PTO-152)					

Art Unit: 1616

#### **DETAILED ACTION**

## Continued Prosecution Application

- 1. The request filed on 3/2/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/987,468 is acceptable and a CPA has been established. An action on the CPA follows.
- 2. Claims 12-28 are pending in this application filed 12/10/97.

#### Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 12-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 5,876,702. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present invention overlaps with that previously claimed. Thus, both the '702 patent and the instant application claim sunscreen cosmetic compositions in the form of emulsions, comprising a UV filter compound containing a sulphonic acid group and an

Art Unit: 1616

emulsifier which is a di- or triglyceryl ester of a fatty acid. The cosmetically or pharmaceutically acceptable superficially hydrophobic inorganic pigments of the instant invention are encompassed by the recitation of "additional UVA and/or UVB filters" in Claims 10 and 19 of the '702 patent since inorganic pigments such as titanium dioxide and zinc oxide, are known UV filters.

#### Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
- 6. Claims 12-19, 21-26 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Gers-Barlag et al. (US 5,876,702).

Gers-Barlag et al.'702 teach cosmetic light protection formulations in the form of o/w emulsions containing UV filters such as 2-phenylbenzimidazole-5-sulphonic acid, sulphonic acid derivatives of benzophenones, sulphonic acid derivatives of 3-benzylidenecamphor, 0.01-20% of emulsifiers such as polyglyceryl 3-diisostearate, polyglyceryl 2-sesquiisostearate, polyglyceryl 2-polyhydroxystearate, inorganic pigments, preferably surface-treated with a water repellent, such as titanium dioxide MT 100 T, and optionally, conventional water-soluble or -dispersible substances. See col. 14, lines 10-22, 40-65; col. 10, lines 58-62; col. 11, lines 19-23; Claims 1, 2 and 10. Gers-Barlag et al.'702 teach a process of making the compositions

Application/Control Number: 08/987,468 Page 4

Art Unit: 1616

by combining the ingredients mentioned above. See Claims 12, 14 and 19. With respect to the limitation "water-resistant" recited in the instant claims, this limitation is inherent in the prior art because the prior art's compositions contain the same ingredients in the same amounts and proportions as the claimed composition. The method of Claim 19 is inherent to the reference because the reference teaches the same method step as claimed in the instant claim, that is, incorporating a superficially hydrophobic inorganic pigment into the oil phase of the emulsion. See col. 14, lines 50-65.

Thus, Gers-Barlag et al.'702 teach each and every limitation of Claims 12-19, 21-26 and 28.

7. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

#### Claim Rejections - 35 USC § 103

- 8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

Art Unit: 1616

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gers-Barlag et al. '702.

Gers-Barlag et al.'702 applied as above.

Although, the reference does not explicitly teach incorporating a hydrophilic inorganic pigment into the water phase in addition to the hydrophobic pigments incorporated into the oily phase, it fully discloses all the elements of the instant invention. Thus, Gers-Barlag et al. '702 teach pigments that are "sparingly soluble or insoluble in water" as well as mixtures of these pigments. See col. 14, lines 40-49. Thus, a combination of hydrophilic and hydrophobic pigments is encompassed by the reference.

The selection of optimal species of inorganic pigments within the reference's generic disclosure is within the skill of ordinary practitioner. If routine experimentation by one of ordinary skill would have led to the use of the particular chemical recited in the claimed composition, the composition is obvious, even though the results obtained by the composition are unexpectedly high. In re Miegel et al. (CCPA 1968) 404 F2d 378, 159 USPQ 716. Same to arrive at an optimum combination. Indiana General Corp. v. Krystinel Corp. (CA 2 1970) 421 F2d 1023, 164 USPQ 321.

11. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gers-Barlag et al. '702 in view of either Billia et al. (US 5,486,353) or Robinson et al. (US 5,306,485).

Art Unit: 1616

Gers-Barlag et al. '702 applied as above.

While teaching polyglyceryl 3-diisostearate, polyglyceryl 2-sesquiisostearate and polyglyceryl 2-polyhydroxystearate emulsifiers, the reference does not explicitly teach polyglyceryl 4-isostearate of the instant claim. However, polyglyceryl 4-isostearate is used in the art of sunscreening cosmetic compositions for the same art-recognized purpose as the polyglyceryl fatty esters of Gers-Barlag et al.'702. See, for example, Billia et al., Examples 1-3 or Robinson et al. at col. 15, Example V.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use polyglyceryl 4-isostearate of Billia et al. or Robinson et al. in emulsions of Gers-Barlag et al.'702 for its art-recognized purpose.

The selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection.

12. Claims 12, 13, 16-21, 24-26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allard et al. (US 5,616,331).

Allard et al. teach sunscreen compositions in the form of o/w emulsions containing inorganic nanopigments, either hydrophobically coated of uncoated, which may be present in the oil phase, or in the aqueous phase of the emulsion, or even in both phases at the same time. See Abstract; col. 3, lines 8-48. The emulsions may also contain organic sunscreen agents such as, for example, 2-phenylbenzimidazole-5-sulfonic acid and salts thereof. See col. 3, lines 54-60. The emulsions of Allard et al. contain 0.5-20% of emulsifiers, such as fatty acid esters of polyols (i.e. compounds prepared by reacting a fatty acid such as stearic or oleic acid, with a polyol such as glycerol or polyglycerol). See col. 5, lines 41-43; col. 6, lines 25-29. The

Art Unit: 1616

emulsions are prepared by mixing the ingredients. See Examples. With respect to the limitation "water-resistant" recited in the instant claims, this limitation is inherent in the prior art because the prior art's compositions contain the same ingredients in the same amounts and proportions as the claimed composition. The method of Claim 19 is inherent to the reference because the reference teaches the same method step as claimed in the instant claim, that is, incorporating a superficially hydrophobic inorganic pigment into the oil phase of the emulsion. See Examples.

Although, the reference does not explicitly teach the claimed combination of components a), b) and c), it fully discloses all the elements of the instant invention.

The selection of optimal species of organic sunscreens and emulsifiers within the reference's generic disclosure is within the skill of ordinary practitioner. If routine experimentation by one of ordinary skill would have led to the use of the particular chemical recited in the claimed composition, the composition is obvious, even though the results obtained by the composition are unexpectedly high. In re Miegel et al. (CCPA 1968) 404 F2d 378, 159 USPQ 716. Same to arrive at an optimum combination. Indiana General Corp. v. Krystinel Corp. (CA 2 1970) 421 F2d 1023, 164 USPQ 321.

13. Claims 14, 15, 22, 23 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allard et al. in view of either Billia et al. or Robinson et al. or Gers-Barlag et al. '702.

Allard et al. applied as above.

Allard et al. do not explicitly teach the emulsifiers of Claims 14, 15, 22, 23 and 27. However, polyglyceryl 4-isostearate of Billia et al. or Robinson et al. and polyglyceryl fatty esters of Gers-Barlag et al. '702 are used in the art of sunscreening cosmetic compositions for

Art Unit: 1616

the same art-recognized purpose as fatty acid esters of polyols disclosed by Allard et al See, for example, Billia et al., Examples 1-3; Robinson et al. at col. 15, Example V; Gers-Barlag et al. '702 at col. 10, lines 58-62.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use polyglyceryl 4-isostearate of Billia et al. or Robinson et al. or polyglyceryl fatty esters of Gers-Barlag et al.'702 in emulsions of Allard et al. for their art-recognized purpose.

The selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection.

14. Claims 12-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gers-Barlag et al. (US 5,725,844) in view of either Grollier et al. (US 5,427,771) or Billia et al. or Robinson et al. or Gers-Barlag et al. '702.

The applied reference (Gers-Barlag et al. '844) has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same

Art Unit: 1616

party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Gers-Barlag et al.'844 teach a waterproof cosmetic composition in the form of O/W emulsion comprising one or more cosmetically acceptable oil- or water-soluble organic UV filter substances, including salts of 2-phenylbenzimidazole-5-sulphonic acid, sulphonic acid derivatives of benzophenones, sulphonic acid derivatives of 3-benzylidenecamphor (col. 7, lines 55-65); one or more cosmetically acceptable hydrophobic inorganic pigments, these pigments being incorporated into the oily phase of the emulsion (col. 3, lines 48-50; col. 5, lines 9-45), emulsifiers, including glyceryl stearate and glyceryl lanolate (Examples 1-4); and other cosmetically acceptable compounds. Gers-Barlag et al.'844 also teach a method for achieving or increasing the water resistance of sunscreen formulations by incorporating the hydrophobic inorganic pigments into the oily phase of the emulsion. See col.4, lines 16-26. With respect to Claim 20, although the reference does not explicitly teach incorporating a hydrophilic inorganic pigment into the water phase in addition to the hydrophobic pigments incorporated into the oily phase, it fully discloses all the elements of the instant invention. Thus, Gers-Barlag et al. '844 teach pigments that are "sparingly soluble or insoluble in water" as well as mixtures of these pigments. See col. 5, lines 9-17. Thus, a combination of

Page 10

Art Unit: 1616

hydrophilic and hydrophobic pigments is encompassed by the reference. The method of Claim 28 is inherently disclosed in the reference. See col. 6, lines 38-40.

Gers-Barlag et al.'844 do not teach polyglyceryl emulsifiers as claimed in the instant claims.

However, Grollier et al. teach using mono- and diesters of fatty acids (C12-C18) and glycerol or polyglycerol (col. 5, lines 27-39) as emulsifiers in sunscreen cosmetic composition. Billia et al., Robinson et al. and Gers-Barlag et al.'702 teach using the polyglyceryl fatty esters as discussed above.

Polyglyceryl and monoglyceryl surface active agents are used in the cited references for the same art recognized purpose.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to substitute monoglyceryl esters of Gers-Barlag et al.'844 for polyglyceryl 4-isostearate of Billia et al. or Robinson et al. or polyglyceryl fatty esters of Gers-Barlag et al.'702 or Grollier et al. for their art-recognized purpose with a reasonable expectation of arriving to the compositions having the same cosmetic properties as disclosed in the Gers-Barlag et al.'844 patent. The selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Art Unit: 1616

Page 11

#### Conclusion

### 15. No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (703) 306-4541. The examiner can normally be reached on Monday to Friday from 9 to 5.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

m/ ~~ 4/25/01 JOSE' G. DEFE SUPERVISORY PATENT EXAMINER

1616